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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,529	08/15/2006	Blandine Bertrand	11123.0110USWO	8706
23552 7590 11/30/2007 MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			EXAMINER DAVIS, BRIAN J	
			ART UNIT 1621	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,529	Applicant(s) BERTRAND ET AL.	
	Examiner Brian J. Davis	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-55 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 25-29 and 36-46 is/are rejected.
- 7) ☒ Claim(s) 25,30-35,39 and 44-55 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/15/06</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: the disclosure does not contain a section entitled: Brief Description of the Drawings. See MPEP 608.01(f). Appropriate correction is required.
2. The disclosure is also objected to because it contains a number of spelling/grammatical errors, for instance, page 1, line 11 (...step[s]...) and page 1, line 24 (...hereunder [sic]...). Appropriate correction is required.
3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is respectfully requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

4. Claim 25 is objected to because of the following informalities: in the label of the diagramed compound of formula (II), the word *or* is misspelled (*ou*). Appropriate correction is required.
5. Claim 39 is objected to because of the following informalities: the claim does not terminate with a period. Claims must begin with a capital letter and end with a period. MPEP 608.01(m). Appropriate correction is required.

6. Claims 44-46 are objected to because of the following informalities: in order to avoid any possible misinterpretation (i.e. as a negative sign) the dash which ends the text and precedes the number should be deleted. Appropriate correction is required.
7. Claim 48 is objected to because of the following informalities: the claim does not terminate with a period.
8. Claim 52 is objected to because of the following informalities: the noun *group* should appear in the penultimate line of the claim before the phrase *consisting of*.
9. Claim 53 is objected to because of the following informalities: the claim terminates with a comma.
10. Applicant's assistance is respectfully requested in correcting any other minor grammatical and/or spelling errors which may be present in the claims.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
12. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear why definitions for variables *j*, *i* and *n* appear in the claim. Diagramed formula (VIIB) of the claim does not contain these variables.
13. Claims 38-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. There is insufficient antecedent basis for the "the catalyst (VII)" limitation in the claims.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17.

18. Claims 25-29 and 36-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over *J. Org. Chem.* (1999), 64, p. 1774-1775.

19. Applicant claims a process for the synthesis of compounds of formula (I) proceeding through compounds of formula (III), then (II) to (I) (claim 1). The dependent claims further define the process.

20. *J. Org. Chem.* (1999), p. 1774-1775 teaches the highly enantioselective hydrogenation of cyclic enamides catalyzed by a Rh-PennPhos catalyst (page 1774, last sentence of first paragraph). Optimized reaction conditions are given as a footnote under Table 1, page 1775.

21. The key to the instant invention is the asymmetric hydrogenation of the enamide compound of formula (III) to yield the compound of formula (II).

22. The cited reference, after first optimizing the conditions, demonstrates the practical usefulness of this asymmetric hydrogenation using a series of cyclic enamides (page 1775, all text and Table 2). The reference explicitly states the substituents on the aromatic ring (in compounds closely structurally related to those of the instant invention) have no effect on the reaction (page 1775, second paragraph, line 5). These sorts of compounds are useful as the amine i.e. the de-N-protected compounds of Table 2 (page 1774, line 1). Such compounds correspond to compounds of instant formula (I).

23. In order for an invention to be obvious, two things must be found in the prior art: 1) the suggestion of the invention, and 2) the expectation of its success. *In re Vaeck*, 947 F2d 488, 492, 20 USPQ2d 1438, 1441 (Fed. Cir. 1991). In the instant case, the

cited reference explicitly suggests that the asymmetric hydrogenation of cyclic enamides is a useful and practical general procedure using the Rh-PennPhos ligand. That suggestion also provides the expectation of success. Thus, the instant asymmetric hydrogenation of the cyclic enamide in order to form the corresponding amine would have been obvious to one of ordinary skill in the art at the time of the invention.

24. Claims 38-46 are included in this rejection as it is well established that merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket*, 33 USPQ 33 (CCPA 1937). *In re Russell*, 439 F2d 1228, 169 USPQ 426 (CCPA 1971).

25.

26. Claims 25-29 and 36-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Org. Letters* (2002), 4(10), p. 1695-1698.

27. As above, applicant claims a process for the synthesis of compounds of formula (I) proceeding through compounds of formula (III) then (II) to (I) (claim 1). The dependent claims further define the process.

28. *Org. Letters* (2002), 4(10), p. 1695-1698 teaches an ortho-substituted BIPHEP ligand and its application in Rh-catalyzed hydrogenation of cyclic enamides (abstract). Optimized reaction conditions are given as a footnote under Table 2, page 1697.

29. The key to the instant invention is the asymmetric hydrogenation of the enamide compound of formula (III) to yield the compound of formula (II).

30. The cited reference, after first optimizing the conditions, demonstrates the practical usefulness of this asymmetric hydrogenation using a series of cyclic enamides

(page 1697, Table 2; page 1698, line 2). These sorts of compounds are useful as the amine i.e. the de-N-protected compounds of Table 2 (page 1696, column 2, last paragraph). Such compounds correspond to compounds of instant formula (I).

31. In order for an invention to be obvious, two things must be found in the prior art: 1) the suggestion of the invention, and 2) the expectation of its success. *In re Vaeck*, 947 F2d 488, 492, 20 USPQ2d 1438, 1441 (Fed. Cir. 1991). In the instant case, the cited reference explicitly suggests that the asymmetric hydrogenation of cyclic enamides is a useful and practical general procedure using the BIPHEP ligand. That suggestion also provides the expectation of success. Thus, the instant asymmetric hydrogenation of the cyclic enamide in order to form the corresponding amine would have been obvious to one of ordinary skill in the art at the time of the invention.

32. Claims 38-46 are included in this rejection as it is well established that merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket*, 33 USPQ 33 (CCPA 1937). *In re Russell*, 439 F2d 1228, 169 USPQ 426 (CCPA 1971)

Allowable Subject Matter

33. Claims 30-35 and 47-55 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

34.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US 7,262,326 B2; WO 99/18065; *J. Am. Chem. Soc.* (2003), 125(12), p. 3534-3543; *J. Org. Chem.* (1999), 64, p. 9381-9385; *J. Org. Chem.* (1998), 63, p. 9590-9593; and *J. Org. Chem.* (1998), 63, p. 7084-6085 are cited to show additional related reactions.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached at 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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 **BRIAN DAVIS**
PRIMARY EXAMINER
Brian J. Davis
November 25, 2007